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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,784	11/03/2004	Kang Li	TNX02-01 (Case 0056)	8464

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,784	LI ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/2/04*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-36 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

1. Claims 2, and 31, drawn to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence encoded by a fragment of SEQ ID NO: 1, wherein the **polypeptide is an agonist** that specifically binds to a mast-cell expressed membrane protein and activates the proteins' cellular function, a vaccine comprising said polypeptide or immunogenic fragment thereof and a pharmaceutically acceptable carrier.

2. Claims 4-5 and 31, drawn to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence encoded by a fragment of SEQ ID NO: 1, wherein the **polypeptide is an antagonist** that specifically binds to a mast-cell expressed membrane protein or its ligand and inhibits the proteins' cellular function, a vaccine comprising said polypeptide or immunogenic fragment thereof and a pharmaceutically acceptable carrier.

3. Claims 6-8, 25-27 and 35-36, drawn to an **agonist antibody** that specifically binds to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence

encoded by a fragment of SEQ ID NO: 1 and a method of producing said antibody using isolated mast cell-expressing membrane proteins or antigenic fragments thereof as an antigen.

4. Claims 6-8, 25-27 and 35-36, drawn to an **agonist antibody** that specifically binds to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence encoded by a fragment of SEQ ID NO: 1 and a method of producing said antibody using isolated host cells that express recombinant mast cell-expressing membrane proteins or DNA expression vectors containing the mast cell-expressing membrane protein gene to express the mast cell-expressed membrane protein as an antigen for producing antibody.

5. Claims 6-8, 25-27, and 35-36, drawn to an **antagonist antibody** that specifically binds to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence encoded by a fragment of SEQ ID NO: 1 and a method of producing said antibody using isolated mast cell-expressing membrane proteins or antigenic fragments thereof as an antigen.

6. Claims 6-8, 25-27 and 35-36, drawn to an ant**agonist antibody** that specifically binds to a purified **polypeptide** comprising an amino acid sequence of SEQ ID NO: 2, a variant of SEQ ID NO: 2, a fragment of SEQ ID NO: 2, an amino acid sequence encoded by an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1, an amino acid sequence encoded by a variant of SEQ ID NO: 1 and an amino acid sequence encoded by a fragment of SEQ ID NO: 1 and a method of producing said antibody using isolated host cells that express recombinant mast cell-expressing membrane proteins or DNA expression vectors containing the mast cell-expressing membrane protein gene to express the mast cell-expressed membrane protein as an antigen for producing antibody.

7. Claims 9-12, and 33-34 drawn to **an isolated polynucleotide** comprising a nucleotide sequence of SEQ ID NO: 1; a variant of SEQ ID NO: 1; a fragment of SEQ ID NO: 1; a nucleotide sequence that encodes a polypeptide having the amino acid sequence selected from the group consisting of: SEQ ID NO: 2; a variant of SEQ ID NO: 2; and a fragment of SEQ ID NO: 2, and a vaccine comprising a pharmaceutically acceptable carrier and a **vector containing a nucleic acid sequence encoding a specific mast cell-expressed membrane protein** or antigenic fragment thereof, wherein the nucleic acid sequence is a sequence selected from the group consisting of SEQ ID NO: 1; a variant of SEQ ID NO: 1; and a fragment of SEQ ID NO: 1.

8. Claim 13, drawn to **a screening method for identifying mast cell-expressing membrane protein against and antagonist** comprising exposing a mast cell-expressed membrane protein to a potential mast cell-expressed membrane protein agonist/antagonist; and determining whether the potential agonist/antagonist interacts with the protein.

9. Claim 14, drawn to a screening **method for determining whether pharmaceuticals are likely to cause undesirable side effects associated with reducing or increasing mast cell activity** when administered to a mammal for the desired indication, comprising: exposing mast cells expressing mast cell-expressed membrane proteins or a purified mast cell-expressed membrane protein to a pharmaceutical; and determining whether the pharmaceutical interacts with the protein or mimics the biological function of the protein ligand.

10. Claims 15-17, drawn to **a method for** blocking or modulating the expression of a cellular mast cell-expressed membrane protein by **interfering with the transcription of a DNA polynucleotide** encoding the mast cell- expressed membrane protein comprising exposing a cell capable of expressing a mast cell-expressed membrane protein to a molecule that interferes with the transcription of a DNA polynucleotide encoding the mast cell- expressed membrane protein, wherein the molecule is antisense nucleotides.

11. Claims 15-17, drawn to **a method for** blocking or modulating the expression of a cellular mast cell-expressed membrane protein by **interfering with the translation of a RNA polynucleotide** encoding the mast cell- expressed membrane protein comprising exposing a cell capable of expressing a mast cell-expressed membrane protein to a molecule that interferes with the translation of a RNA polynucleotide encoding the mast cell- expressed membrane protein, wherein the molecule is RNAi nucleotides, and ribozymes.

12. Claims 18-21, and 24, drawn to **a method for diagnosing** the predisposition of a patient to develop diseases caused by unwanted activity of cells expressing mast cell-expressed membrane proteins, comprising: collecting a cell, tissue, or body fluid sample known to contain few if any mast cell-expressed membrane proteins from a patient; analyzing the tissue or body fluid for the presence of mast cell-expressed membrane proteins in the tissue; and predicting the predisposition of the patient to certain immune diseases based upon the presence of mast cell-expressed membrane proteins in the tissue or body fluid.

13. Claims 23, drawn to **a method for preventing or treating** a specific mast cell-expressed membrane protein mediated disease in a mammal comprising administering a specific disease preventing or treating amount of a mast cell-expressed membrane protein agonist to the mammal, wherein the agonist is an **agonist antibody**.

14. Claims 23, drawn to **a method for preventing or treating** a specific mast cell-expressed membrane protein mediated disease in a mammal comprising administering a specific disease preventing or treating amount of a mast cell-expressed membrane protein antagonist to the mammal, wherein the agonist is an **antagonist antibody**.

15. Claims 28-29, drawn to a **method for isolating and purifying mast cell-expressed membrane proteins** from recombinant cell culture, contaminants, and native environments using antibody.

16. Claim 30, drawn to a **transgenic knockout animal** whose genome comprises a heterozygous or homozygous disruption in its endogenous mast cell-expressed

membrane protein gene that suppresses or prevents the expression of biologically functional mast cell-expressed membrane proteins.

17. Claim 32, drawn to a **method for immunizing a mammal** against mast cell or other mast cell-expressed membrane protein mediated diseases comprising injecting one or more **mast cell-expressed membrane proteins** or immunogenic fragments thereof into the mammal.

The inventions listed as Groups 1-17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The WO98/30582 publication teaches a variant of the claimed polypeptide of SEQ ID NO: 2 such as SEQ ID NO: 18 encoded by nucleic acid AAV40509 (see page 82, in particular). The reference protein is 174 amino acids identical to SEQ ID NO: 2 and fragments thereof (see page 33, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

Linking claims 1 and 3 will be examined along with the elected Group if any one of Group 1-6 is elected. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 3.

Linking claim 22 will be examined along with the elected Group if Group 13 or 14 is elected. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim 22.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

III. Accordingly, Groups 1-17 are not so linked as to form a single general inventive concept and restriction is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product claim are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message

may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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